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Attorney Docket No.: 5540-1ACXCT2

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Continuation of Vandepopuliere *et al.*

Serial No.: 09/922,824

Group Art Unit: 1761

Filed: 6 August 2001

Examiner: A. Weier

For: METHOD OF CONTROLLING SALMONELLA IN SHELL EGGS

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**TRANSMITTAL OF APPEAL BRIEF
(PATENT APPLICATION--37 C.F.R. § 1.192)**

1. Transmitted herewith, in triplicate, is the APPEAL BRIEF in this application, with respect to the Notice of Appeal filed on November 15, 2002.
2. This application is filed on behalf of
☐ a small entity
A verified statement ☐ is attached; ☐ was already filed.
3. Pursuant to 37 C.F.R. § 1.17(c), the fee for filing the Appeal Brief is:

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Respectfully submitted,

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**RESPONSE UNDER 37 C.F.R. § 1.116
EXPEDITED PROCEDURE - EXAMINING GROUP 1761**

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APPELLANTS' BRIEF ON APPEAL UNDER 37 C.F.R. §1.192

Sir:

This Appeal Brief is filed pursuant to the "Notice of Appeal to the Board of Patent Appeals and Interferences" filed November 15, 2002.

Real Party In Interest

The University of Missouri System at Columbia, Missouri, is the assignee of the above-named patent application, and Michael Foods, Inc., is a licensee of The University of Missouri having certain rights in the application.

Related Appeals and Interferences

Appellants are aware of no appeals or interferences that would be affected by the present appeal.

Status of Claims

Appellants appeal the final rejection of Claims 24-30, which as of the filing date of this Brief, remain under consideration. The claims at issue are attached hereto as Appendix A.

Status of Amendments

In the present case, a Preliminary Amendment was filed August 6, 2001; the Preliminary Amendment has been entered. Furthermore, an Amendment was filed February 25, 2002, which did not present amendments to the claims. A Request for Reconsideration was filed August 19, 2002, which did not amend the claims.

Summary of the Invention

The present invention relates to thermally processed shell eggs. More particularly, the present invention provides shell eggs which have reduced levels of *Salmonella enteritidis* in the albumen and the yolk of the shell egg and which retain their functional properties, having no more than insignificant coagulation of either the yolk or the white (the albumen). The delicate balance between microbial kill and functionality of the shell eggs was first discovered by the present inventors and described in the present application. Such a balance is reflected in Figure 1 of the present application, which is reproduced below, where the inventors discovered that sufficient thermal treatments could be provided to a shell egg to kill *Salmonella* while retaining the egg's highly desirable functional properties. In contrast, previous investigators thought that higher thermal treatments would be required to kill *Salmonella*. These higher thermal treatments are reflected by the "*Expected Salmonella*" line of Figure 1.

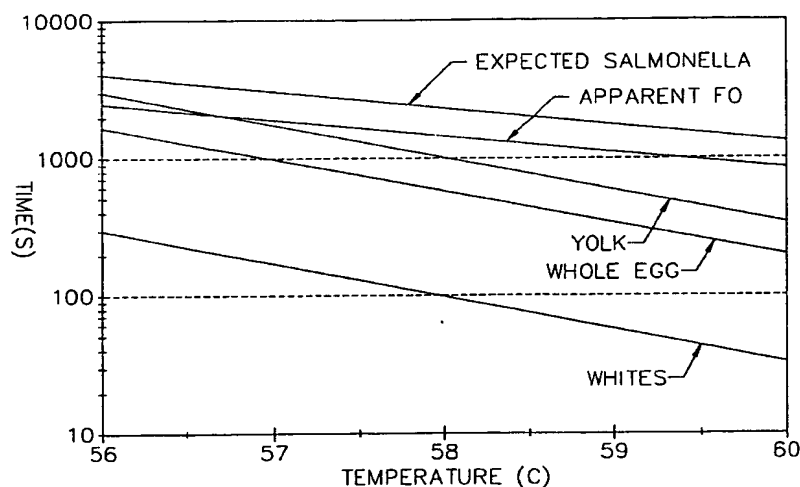


FIG. 1.

In particular, independent Claims 24, 29 and 30 provide for thermally treated shell eggs which receive a thermal treatment that is sufficient to insure a reduction in *Salmonella enteritidis* but which is insufficient to cause more than insignificant coagulation of the albumen and the yolk of the shell egg (e.g., is less than a thermal treatment defined by a point above the *Expected Salmonella* line of Figure 1). For example, a thermal treatment may produce a shell egg having a reduction in *Salmonella*; however, this same thermal treatment may be too severe, such that the shell egg falls outside the claims, in that it results in an egg having more than insignificant coagulation of the albumen and/or the yolk. Thus, the present claims place both lower and upper limits on the thermal treatment which may be received by the shell egg and still remain within the claims.

Furthermore, each of the independent claims recites that the thermal treatment must also be sufficient to provide at least a 5 log cycle (5D) reduction in *Salmonella enteritidis*. In particular claims, the reduction in *Salmonella enteritidis* must be at least a 7D reduction (Claim 25) and in

further claims the reduction must be at least a 9D reduction (Claim 26). Finally, certain of the claims also require that the shell egg have an extended refrigerated shelf life (Claim 28), having "essentially natural proportion of indigenous gases therein" (Claim 29) or that the thermal treatment be "applied under atmospheric pressure" (Claim 30).

Issues

I. Are Claims 24-30 properly rejected under 35 U.S.C. §102 as being anticipated by U. S. Patent No. 5,431,939 to Cox *et al.* (hereinafter "Cox" or "the '939 patent")?

II. Are Claims 24-30 properly rejected for double patenting of the obviousness type over Claims 1-7 of U.S. Patent 6,303,176. Appellants assume this rejection has been overcome in view of the terminal disclaimer filed August 19, 2002, but as withdrawal was not indicated in the Advisory Action, it is requested that the Examiner explicitly indicate in the Examiner's Answer whether the double-patenting rejection has been withdrawn.

Grouping of Claims

Appellants submit that the claims do not stand or fall together, and the following claim groupings are appropriate as each of the claim groupings is separately patentable.

The Group I claims include Claims 24 and 27 and are directed to shell eggs which have received a thermal treatment sufficient to cause a 5D reduction in *Salmonella enteritidis*, but which is insufficient to cause more than insignificant coagulation of the albumen and the yolk of the shell eggs. The Group I claims stand or fall together.

The Group II claim is Claim 25, which depends from the Group I claims and further requires that the reduction be a 7D reduction.

The Group III claim is Claim 26, which depends from the Group I claims

and further requires that the reduction be a 9D reduction.

The Group IV claim is Claim 28, which depends from the Group I claims and further requires that the shell egg have a shelf life of at least about 12 weeks under refrigerated conditions.

The Group V claim is independent Claim 29, which recites that the shell egg have essentially its natural proportion of indigenous gases.

The Group VI claim is independent Claim 30, which recites that the thermal treatment is provided at atmospheric pressure.

Argument

I. Introduction

Each of the claims of the present application stands rejected as anticipated by the '939 patent. However, as discussed below, each of the claims is patentable over the '939 patent for at least three separate reasons. First, the '939 patent does not disclose all of the recitations of the claims. Second, the '939 patent did not put the present invention in the possession of the public and was, at most, an accidental anticipation of the present claims. Finally, the Examiner has used hindsight reconstruction of the '939 patent in asserting that the '939 patent anticipates the present claims and has failed to sufficiently consider Appellants' substantial evidence that those of ordinary skill in the art would not have appreciated the '939 patent as disclosing the claimed invention.

Appellants will first discuss the legal standards applicable to all of the rejections, then briefly discuss the '939 patent and its related continuation-in-part patent as they relate to the present claims, and then Appellants will address each of the claim groups individually.

II. The Legal Standards for Anticipation

Anticipation requires that each and every element of the claim is found in a single prior art reference. *W. L. Gore & Associates Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983). Stated another way, all material elements of a claim must be found in one prior art source. *In re Marshall*, 198 U.S.P.Q. 344 (C.C.P.A 1978). A finding of anticipation further requires that there must be no difference between the claimed invention and the disclosure of the cited reference as viewed by one of ordinary skill in the art. See *Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Additionally, the cited prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public. *In re Brown*, 329 F.2d 1006, 1011, 141 U.S.P.Q. 245, 249 (C.C.P.A. 1964). Thus, the prior art reference must adequately describe the claimed invention so that a person of ordinary skill in the art could make and use the invention.

In some circumstances, an element may not be expressly disclosed by the prior art reference, but may be inherent in the disclosure. The Court of Appeals for the Federal Circuit has set forth the Examiner's burden in establishing a *prima facie* case of inherency as a two-part test. *In re Robertson*, 169 F.3d 743; 49 U.S.P.Q.2d 1949 (Fed. Cir. 1999). Specifically, the Court stated:

If a particular prior art reference does not expressly set forth a particular element of the claim, that reference still may anticipate if that element is "inherent" in its disclosure. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, **and that it would be so recognized by persons of ordinary skill**. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

In re Robertson, 169 F.3d at 745, 49 U.S. P.Q.2d at 1950-51; *emphasis added, quotation and citations omitted*. Thus, under the *Robertson* test, the Examiner has the burden of providing extrinsic evidence establishing that (1) the alleged inherent feature is "necessarily present in the thing described in the reference", and (2) "it would be so recognized by persons of ordinary skill." The *Robertson* Court described these as "critical principles" informing the inherency inquiry. *In re Robertson*, 169 F.3d at 745, 49 U.S. P.Q.2d at 1950-51.

The Federal Circuit and its predecessor court, the Court of Claims and Patent Appeals, have addressed the standard to support a rejection for inherency on previous occasions as well. For example, in *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 20 U.S.P.Q.2d 1746 (Fed. Cir. 1991), the Federal Circuit stated:

To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. . . . Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient. This modest flexibility in the rule that "anticipation" requires that every element of the claims appear in a single reference accommodates situations where the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges.

Continental Can Co., 948 F.2d at 1268-69, 20 U.S.P.Q.2d at 1749-50; *emphasis added, citations omitted*; see also *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 34 U.S.P.Q.2d 1565 (Fed. Cir. 1995), "The disclosure need not be

express, but may anticipate by inherency **where it would be appreciated by one of ordinary skill in the art.**" *Glaxo Inc.*, 52 F.3d at 1047, 34 U.S.P.Q.2d at 1567).

Further, in *In re Oelrich*, 666 F.2d 578, 212 U.S.P.Q. 323 (C.C.P.A. 1981), it is stated that inherency may be found if the "disclosure is sufficient to **show** that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient." *In re Oelrich*, 666 F.2d at 581, 212 U.S.P.Q. at 326; *emphasis added*. Finally, as Appellants have previously noted, the United States Supreme Court has stated that "[a]ccidental results, not intended and **not appreciated**, do not constitute anticipation." *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 66 (1923)(*emphasis added*).

As discussed in more detail below, it is Appellants' position that the rejection in the Final Official Action does not satisfy the burden for establishing anticipation by the '939 patent, either expressly or inherently, under § 102 (e).

III. **The '939 Patent**

The '939 patent to Cox *et al.* describes the "hyperpasteurization" of food. In particular, the '939 patent describes hyperpasteurization of shell eggs as subjecting the shell eggs "to hypobaric pressure to substantially disinfuse indigenous dissolved gases." '939 patent, col. 14, lines 62-65. In fact, Figures 1 through 9 all describe systems or processes for hyperpasteurization which apply a hypobaric pressure to the product being processed. See '939 patent, Figures 1-9. The '939 patent then introduces its "examples" of hyperpasteurization stating:

As discussed above, hyperpasteurization may often advantageously be carried out at an elevated temperature. The following example shows that one exemplary food -- fresh, raw, shell eggs -- can be held at preferred temperatures for appropriate periods

of time without significantly altering desirable characteristics of the eggs. This is apparent from FIG. 10 which also shows the unwanted changes occur if the time/temperature conditions heretofore proposed by others are employed.

Specific examples involving the treatment of raw, fresh, shell eggs follow.

'939 Patent, col. 15, lines 51-61. As is illustrated by the above portion of the '939 patent, the majority of the '939 patent examples are examples of hyperpasteurization which is expressly described by the '939 patent as involving placing the shell eggs under hypobaric pressure.

Furthermore, with regard to Figure 10 of the '939 patent, the processing conditions illustrated in Figure 10 of the '939 patent as "SALMONELLA DESTROYED" correspond to the *Expected Salmonella* line of Figure 1 of the present application. Thus, the '939 patent teaches that thermally treated shell eggs which were treated by thermal treatments below the *Expected Salmonella* line of Figure 1 of the present application would not receive sufficient thermal treatment to "destroy" *Salmonella*.

Additionally, the '939 patent is the parent to United States Patent No. 5,589,211 (hereinafter "the '211 patent"). The '211 patent is a continuation-in-part of the '939 patent and relates to processing without the use of hypobaric pressures. Significantly, however, the '211 patent has removed Figure 10 which indicates the degree of thermal processing required to achieve *Salmonella* destruction taught by the '939 patent. While the '211 patent is not prior art to the present application, it does indicate that even Cox *et al.* realized that the teachings of the '939 patent were incorrect and had to be revised because Figure 10 suggests that pasteurization of shell eggs can only be achieved at unacceptably high thermal treatments (e.g., thermal treatments which may result in more than insignificant coagulation of the albumen and/or the white). Thus, Appellants submit that Cox *et al.* themselves understood that the '939 patent was not enabling to teach one of skill in the art how to provide thermally treated, pasteurized shell eggs as the figures relating to the early work described in the

'939 patent were removed from subsequent Cox *et al.* patents (patents which are not prior art to the present application).

IV. The Claim Rejections

Pending Claims 24-30 stand finally rejected as being anticipated by U.S. Patent No. 5,431,939 to Cox *et al.* The Final Official Action states that Cox *et al.* discloses an egg that "[reads] on the instant product claims." (Final Official Action, page 3, line 13). The Final Official Action further states that the "temperature and time treatment used in Cox *et al.* (internal temperature of 54.4 C for 45 minutes) is at least enough to accomplish what Applicants were able to accomplish regarding the extent of Salmonella kill called for in the instant claims (see Table 2, page 16 and 17, first paragraph)." (Final Official Action, page 3, last 4 lines). It is further contended that:

Whether or not Cox *et al.* was aware of the product produced, the egg product of Cox *et al.* falls within the claim limitations as set forth, absent a showing to the contrary. The recitation of a newly discovered function or property (or in the instant case, perhaps, degree of pasteurization effected) inherently possessed by the prior art does not cause a claim drawn to such new function or property to distinguish over the prior art. Where the Patent Office has reason to believe that limitations asserted to be critical for establishing novelty may, in fact, be inherent characteristics of the prior art, it possesses authority to require applicant to prove that the product of the prior art does not possess such characteristics relied on. In re Swinehard.

(Final Official Action, page 5, lines 5-13). However, Appellants submit that each of the pending claims is patentable over the '939 patent for the reasons discussed below.

A. The Group I Claims are Patentable over the '939 Patent

The Group I claims include Claims 24 and 27, which stand or fall together. Claim 24 is an independent claim which recites:

24. A thermally treated shell egg wherein said shell egg received a thermal treatment sufficient to cause at least about a 5D reduction in *Salmonella enteritidis* in the albumen and in the yolk of said shell egg but insufficient to cause more than insignificant coagulation of the albumen and the yolk of said shell egg.

Thus, the Group I claims are drawn to thermally treated shell eggs that "received a thermal treatment sufficient to cause at least about a 5D reduction in *Salmonella enteritidis* in the albumen and in the yolk of said shell egg" and which "is insufficient to cause more than insignificant coagulation of the albumen and the yolk of said shell egg." The claimed invention is not to be found, expressly or inherently, in the '939 patent. In particular, the claimed invention is not anticipated by Example 1 of the '939 patent. In contrast to the teachings of the '939 patent, Appellants have employed thermal treatments with intact shell eggs to achieve reductions in *Salmonella* therein, at conditions previously thought insufficient to kill *Salmonella*, without unduly impairing egg quality and function.

1. The '939 Patent Does Not
Disclose the Recitations of the Group I Claims

Appellants submit that the Final Official Action has failed to establish that each of the recitations of the claims is disclosed, either explicitly or inherently, in the '939 patent. In particular, the '939 patent fails to explicitly or inherently disclose to one of ordinary skill in the art time and temperature conditions that would achieve a shell egg having the recited features, *e.g.*, a thermal treatment sufficient to result in at least a 5D reduction in *Salmonella enteritidis* in the albumen and in the yolk of the shell egg, but insufficient to cause more than insignificant coagulation of the albumen and the yolk of the shell egg.

The outstanding rejection relies on Example 1 of the '939 patent as disclosing a time and temperature treatment of 57 °C for 40 to 45 minutes

(Final Official Action, page 3, last 4 lines). This time period was only sufficient to bring the internal egg temperature up to the target temperature of 54.4°C ('939 patent, Col. 16, lines 16-18) and, as discussed further below, would be insufficient to produce the recited reductions in *Salmonella* in the egg. Time and temperature treatments of 57 °C for 1.5 hours (5400 seconds) and 59.4°C for 1.25 hours (4500 seconds) were also described in Example 1 of the '939 patent; however, these conditions are not relied on by the Examiner in the outstanding rejection. These longer time periods provide thermal treatments that may result more than "insignificant coagulation" of the yolk and/or the white of the shell egg (see, specification of the present application, page 6, lines 23-26) and/or a loss of functionality (see, Supplemental Ball Declaration submitted with Appellants' response of February 25, 2002 and executed June 16, 1998, ¶ 7). Thus, Example 1 does not explicitly provide thermal treatments (time x temperature) that produce the claimed shell eggs having at least about a 5D reduction in *Salmonella enteritidis* in the albumen and yolk and having no more than insignificant coagulation of the albumen and the yolk of the shell egg.

In the following arguments, Appellants will focus on the thermal treatments specifically relied upon in the Final Official Action (*i.e.*, 57°C for 40 to 45 minutes). If the Examiner wishes to rely on any of the other thermal treatments described in the '939 patent, Appellants reserve the right to address these specific time and temperature conditions on the record.

Appellants submit that the specific conditions relied on in the Final Official Action (57°C for 40 to 45 minutes) are indicated by the '939 patent as insufficient to provide "Salmonella Destruction" (See, the '939 patent, Figure 10). Figure 10 of the '939 patent describes when *Salmonella* destruction takes place. The conditions relied on in the Final Official Action fall below the *Salmonella* destruction line of Figure 10 of the '939 patent. Thus, it seems

clear, that whatever the reason, the relied on conditions from the '939 patent are reported by the '939 patent as insufficient for *Salmonella* destruction.

Thus, the examples of the '939 patent cannot be considered to inherently describe each of at least a 5D reduction in *Salmonella enteritidis* and a thermal treatment which does not result in more than insignificant coagulation of the albumen and the yolk of the shell egg (e.g., does not exceed the *Expected Salmonella* line of Figure 1). As such, Appellants submit that the Group I claims are not anticipated by the '939 patent.

The Final Official states that the "temperature and time treatment used in Cox *et al.* (internal temperature of 54.4 C for 45 minutes) is at least enough to accomplish what Applicants were able to accomplish regarding the extent of Salmonella kill called for in the instant claims (see Table 2, page 16 and 17, first paragraph)." (Final Official Action, page 3, last 4 lines). Appellants respectfully disagree. The '939 patent does not disclose (either expressly or inherently) or enable one skilled in the art to produce the presently-claimed shell eggs. As described above, Example 1 of the '939 patent discloses a time-temperature study in which intact shell eggs were heated in a peanut oil bath or a water bath preheated to 57° C (134.6° F) from a temperature of 4.4° C (40 °F) ('939 patent, Col. 15 line 64 to Col 16 line 2). The internal temperature of the eggs was monitored at 5-minute intervals ('939 patent, Col. 16, lines 3-5). This study found that eggs heated at 57° C for a time between 40 and 45 minutes reached the internal target temperature of 54.4° C (129.9°F) and showed a thickening of the white ('939 patent, Col. 16, lines 16-20). This study and, apparently, some unspecified other study, further found that eggs heated for 1.5 hours at 57° C exhibited similar functionality to eggs heated at 59.4° C for 1.25 hours ('939 patent, Col. 16, lines 31-33).

The eggs described in Table 2 of the present application started off at an internal temperature of about 23 or 24 °C. In contrast, the eggs described in Example 1 of the '939 application had a starting internal temperature of

4.4°C. Accordingly, the times and temperatures in Example 1 of the '939 patent cannot be directly compared with the times and temperatures in Table 2 of the present application. **In Example 1 of the '939 patent, 40 to 45 minutes at 57°C was only sufficient to bring the egg up to the internal target temperature of 54.4°C ('939 patent, Col. 16, lines 16-18). As discussed in the following paragraph, these conditions would not be sufficient to produce a shell egg having at least a 5-log reduction in *Salmonella*, as presently claimed.**

As indicated in Table 2 of Schuman *et al.*, (1997) *J. Applied Microbiology* **83**:438, (copy enclosed at Appendix B), shell eggs having a mean internal starting temperature of 21.1 and 19.6 °C, exhibited only a 2.0-2.5 log reduction in viable *Salmonella enteritidis* populations during the 35 minute "come up" time in a 57°C waterbath (see Schuman *et al.*, page 441, Col. 2, lines 3-5). The shell egg produced by the conditions cited by the Examiner in Example 1 of the '939 patent (57 °C for 40-45 minutes from a starting temperature of 4.4 °C) only received a thermal treatment sufficient to bring the egg to the internal target temperature of 54.4°C ('939 patent, Col. 16, lines 16-18) and in view of the teachings of Schuman *et al.* clearly would have significantly less than a 5-log reduction in *Salmonella* during the "comp up" phase.

In sum, the shell egg disclosed by Example 1 of the '939 patent, which has been heated in a 57°C peanut oil or water bath for 40-45 minutes from a starting temperature of 4.4°C **does not** anticipate the present invention, either expressly or inherently. The shell egg in Example 1 of the '939 patent **would not** have the claimed reductions in *Salmonella*. Thus, the disclosure of the '939 patent upon which the Final Official Rejection is based (*i.e.*, a shell egg heated at 45 minutes in a 57°C waterbath to reach an internal target temperature of 54.4°C) does not anticipate the Group I claims.

2. The '939 Patent Would Not Have Been
Viewed as Disclosing the Group I Claims

The rejection in the Final Official Action which asserts that the '939 patent inherently discloses the present invention is deficient in that the '939 patent does not "show" to one of ordinary skill in the art that the claimed thermally pasteurized egg would be "the natural result" of the time-temperature curves in the cited example of the '939 patent. See *In re Oelrich*, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Under the *Robertson* test, the Examiner has failed both to (1) provide extrinsic evidence demonstrating that the claimed shell egg would necessarily flow from the '939 patent (e.g., the time-temperature studies of Example 1 of the '939 patent), and (2) show that one skilled in the art would immediately so recognize. The instant case is not one where "modest flexibility in the rule" that each and every claim element must be disclosed by the cited reference is appropriate. See *Continental Can, Co. vs. Monsanto Co.*, 948 F.2d 1264, 1268-69, 20 U.S.P.Q.2d 1746, 1749-50 (Fed. Cir. 1991). Likewise, the '939 patent does not represent a situation in which "the common knowledge of the technologist is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges." *Id.*

The Examiner cites dicta from *In re Swinehart*, 439 F.2d 210, 169 U.S.P.Q. 226 (C.C.P.A. 1971) for the proposition that "[w]here the Patent Office has reason to believe that limitations asserted to be critical for establishing novelty may, in fact, be inherent characteristics of the prior art, it possesses authority to require applicant to prove that the product of the prior art does not possess such characteristics relied on." (Final Official Action, page 9-13). However, the Examiner does not respond to the controlling authority from the United States Supreme Court that holds that "accidental results" that are "not appreciated" cannot be the basis of anticipation. See *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 66 (1923).

Appellants respectfully submit that the outstanding rejection does not set forth a *prima facie* case of inherency. Appellants further assert that in the absence of a *prima facie* case, Appellants are not required to prove that the '939 patent did not achieve a pasteurized shell egg as presently claimed. Nonetheless, as Appellants have discussed in the previous section, the example from the '939 patent relied upon in the Final Official Action (*i.e.*, a shell egg heated for 40 to 45 minutes in a 57°C bath to reach an internal temperature of 54.4°C) has been distinguished from the presently-claimed egg in that the heated shell egg of Example 1 of the '939 patent does not achieve a shell egg having at least a 5-log reduction in *Salmonella*.

Moreover, in Example 1 of the '939 patent there was no attempt to ascertain microorganism levels, much less *Salmonella*, within the heat-treated eggs (See the Supplemental Ball Declaration submitted with Appellants' response of February 25, 2002 and executed June 16, 1998, ¶ 3). Likewise, Example 1 does not evaluate whether there is a reduction in microbial populations in the shell egg as a result of the heating process. Any reduction in *Salmonella* population in the shell eggs described in Example 1 of the '939 patent would not have been appreciated by one of ordinary skill in the art by reading the '939 disclosure. Appellants further submit that similar problems are present in the other examples of the '939 patent. See *e.g.*, the Supplemental Ball Declaration ¶¶ 3-6, (indicating that the studies described in Example 3 of the '939 patent do not provide any meaningful data on the effects of thermal treatment on microbial kill in intact eggs).

Thus, the examples of the '939 patent do not teach and enable the presently-claimed shell eggs. See, *e.g.*, the Supplemental Rule 132 Declaration of Hershell R. Ball, Jr., Ph.D. If, fortuitously, any of the thermal treatments described in the examples of the '939 patent resulted in the presently claimed shell eggs, it would not have been appreciated by one of ordinary skill in the art by reading the '939 disclosure. Indeed, in view of the '939 reference when taken as a whole and the state of the art, one of ordinary

skill would not have viewed the '939 patent as teaching or enabling a shell egg having at least a 5-log reduction in *Salmonella* utilizing thermal treatments to provide the shell egg as presently claimed in the Group I claims.

For example, even assuming *arguendo* that the examples of the '939 patent disclose times and temperatures corresponding to those which would provide the claimed shell eggs if carried out according to the teachings of the present application, Figure 10 of the '939 patent teaches that the time and temperature conditions used in the examples of the '939 patent are not effective for pasteurization. Figure 10 of the '939 patent teaches that thermal treatments at or above the *Salmonella* destruction curve ("Expected *Salmonella*" line of Figure 1 of the present application) must be applied to pasteurize shell eggs. Cox *et al.* did not realize that less severe thermal treatments could be employed prior to filing the previously-cited continuation-in-part application (U.S. Patent No. 5,589,211). Such less severe thermal treatments provide a different shell egg than those described as effective for the destruction of *Salmonella* in the '939 patent. As described in the present application (at page 6, lines 23-26), the treatments indicated by Figure 10 are likely to result in coagulation or other losses in functionality in the treated shell egg (see the Supplemental Ball Declaration, ¶ 7) and, thus, eggs subject to such treatment fall outside of the present claims. Significantly, Figure 10 was omitted from the Cox *et al.* CIP application (the '211 patent).

The Final Official Action states that there may be other reasons why Figure 10 was omitted from the CIP application (Final Official Action, page 5, second paragraph). Nonetheless, the inclusion of Figure 10 in the '939 patent is significant because the '939 patent must be assessed as a whole for what it fairly teaches one of ordinary skill in the art. As discussed above, Figure 10 would teach one of ordinary skill in the art that pasteurization was not achieved in Example 1 of the '939 patent by heating an egg for 40 to 45 minutes at 57°C to an internal target temperature of 54.4°C (*i.e.*, a thermal treatment below the *Salmonella* destruction line of Figure 10 of the '939

patent) and would, in fact, teach one of ordinary skill in the art to process shell eggs in a manner which results in a shell egg which falls outside the shell egg claimed in the Group I claims.

The Appellants are aware that one may not attempt to claim a prior art composition on the basis of a newly-found characteristic or property thereof. For example, if a chemical compound has been purified and described in the prior art, an applicant may not claim the prior art compound itself on the basis of a new use or discovered property. The present rejection may be readily distinguished from this situation.

The '939 patent does not disclose a prior art composition or product for which Appellants have merely discovered a new property or use. The '939 patent does not disclose the claimed pasteurized shell egg having at least a 5D reduction in *S. enteritidis* therein and having no more than insignificant coagulation of the albumen and yolk. **Appellants have discovered the claimed product itself, not merely a new characteristic or use thereof.**

The cited examples of the '939 patent simply carry out routine time-temperature studies for shell eggs placed within a water or oil bath. The purpose of these experiments is not stated in the '939 patent. Example 1 appears to be a preliminary evaluation of the "come up" time to heat the internal contents of the egg to a target temperature and/or studies which resulted in the plots of Figure 10 of the '939 patent. Example 1 of the '939 patent does **not** disclose or suggest to one of ordinary skill that **any** reduction in *S. enteritidis* was achieved, and certainly does not disclose or suggest the claimed reductions in *S. enteritidis*. "[A]ccidental results, not intended and not appreciated, do not constitute anticipation." *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 66 (1923).

Accordingly, Appellants submit that one of ordinary skill in the art would **not have the slightest hint** that a particular undisclosed time point in Example 1 of the '939 patent might correspond to an effective thermal treatment for pasteurizing a shell egg to achieve at least a 5D reduction in

Salmonella and without significant coagulation of the albumen and yolk (e.g., below the *Expected Salmonella* line of Figure 1), as presently claimed. The invention of the Group I claims can only be found within Example 1 of the '939 patent, if at all, through the impermissible use of hindsight. Without using the present application as a guide, one of ordinary skill in the art would have no inkling as to an effective thermal treatment for pasteurizing a shell egg without significant coagulation thereof, as is presently claimed. Accordingly, Appellants submit that the Group I claims are patentable over the '939 patent for these additional reasons.

3. The Official Actions Do Not Sufficiently
Address Appellants' Evidence
As to How the '939 Patent Would Have Been Viewed

In addition to the reasons discussed above, Appellants submitted and discussed in the Amendment dated February 25, 2002, the Van Lith *et al.*, Stadelman *et al.*, and Hou *et al.* references (items 51, 59 and 61 on the PTO-1449 form submitted August 6, 2001) which indicate that as recently as 1996, the state of the art suggested that thermal treatments are not effective to produce a pasteurized shell egg. In particular, these three publications provide additional evidence that the success of the present invention in effectively pasteurizing intact shell eggs would have been unexpected to those of ordinary skill in the art at the time of invention. All three references were published after the filing date of the present invention, and all teach away from the present invention.

Turning to the particular evidence provided by these references, Van Lith *et al.*, (1995) *Archiv. fur Geflugelkunde* **59**, 157-160, evaluated the effects of heating chicken shell eggs in a water bath heated at 57 °C for 25-30 minutes on *Salmonella* kill. These investigators found that only a 3D reduction in *Salmonella* could be achieved by heating at 57 °C for 30 minutes,

and further found that longer heating was not feasible as it would harm the quality of the egg. Specifically, Van Lith *et al.* state:

From the calculated internal temperatures, it could already be expected, that this heat treatment in water [at 57° C] never could be effective to destroy *Salmonella* bacteria if present. The results in Table 3 confirm this finding. (page 159, Col. 1, paragraph 5; emphasis added).

Pasteurization of table eggs at 57 °C using the method originally patented for the treatment of duck eggs to eliminate *Salmonellae* did not result in *Salmonella* free eggs. As the albumen coagulates strongly already at the temperature and time combination above 57°C and 20 minutes, no beneficial effect from higher temperatures of longer times can be expected. (page 159, Col. 1, paragraphs 7 and 8; emphasis added).

The pasteurization treatment proved to be ineffective and this could have been predicted by measuring the internal temperatures in the egg during the heat treatment. The results were confirmed by the microbiological tests, which showed that *Salmonellae* survived the treatment of eggs at 57 °C for 30 minutes. Van Lith, *et al.*, page 159, Col. 2, paragraphs 4 and 5, emphasis added.

Similarly, Hou *et al.*, (1996) *Food Microbiology* 13:93-101, also found that "[e]ggs pasteurized in a 57 °C circulating water-bath for 25 min gave a reduction in *S. enteritidis* ATCC 13076 of about 3 log cycles." Hou, *et al.*, Abstract; emphasis added. This reference further explains:

The use of a 57 °C water-bath gave a maximum temperature increase without protein denaturation for up to 30 min. Prior exploratory work indicated that extended incubation times for more than 30 min often resulted in denatured egg white proteins as a result of the egg white reaching a critical temperature of 57 °C (data not shown). Therefore, the maximum allowable destruction of *S. enteritidis* ATCC 13076 in shell eggs by water-bath heating without egg white denaturation was approximately 3 logs (Fig 1.) (page 97, Col. 2, line 12 to page 98, Col. 1, line 10; emphasis added).

Likewise, Stadelman *et al.*, (1996) *Poultry Sci.* **75**:1122, report that their results "confirmed the observation by Van Lith *et al.* (1995) of the partial reduction (3-log cycles, Figure 4) of the inoculated cells during water bath heating and of protein denaturation of egg proteins during extended incubation at [57 °C]." Stadelman, *et al.*, page 1124, Col. 1, paragraph 2.

In sum, the Van Lith *et al.*, Stadelman *et al.*, and Hou *et al.* references all teach away from the thermally treated shell egg of the present invention. The Appellants have provided a method of heating shell eggs so as to achieve at least a 5D reduction in *Salmonella* without impairing egg functionality, and which is less severe than the thermal treatments which are disclosed by Cox *et al.* in the '939 patent. Clearly, as indicated by the three references discussed above, such a result has eluded others skilled in the art.

In the Final Official Action, the Examiner states that "Hou does set forth that prior art treatment in a water bath at 57 C for greater than 30 minutes 'often resulted in denatured egg white proteins,'" but contends that "this does not mean that the egg white has denatured in every case (but only 'often')". (Final Official Action, page 4, lines 10-12). Appellants submit that, at most, it would be a haphazard occurrence if Hou achieved eggs that fell within the scope of the instant claims. Such an unpredictable and haphazard event would not rise to the level of an anticipatory disclosure. As held by the United States Supreme Court "[a]ccidental results, not intended and not appreciated, do not constitute anticipation." *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 66 (1923)(*emphasis added*). Even if, for the sake of argument, Hou occasionally achieved a shell egg that fell within the scope of the present claims, this reference did not disclose such a shell egg to those of ordinary skill in the art and did not enable those skilled in the art to reproducibly achieve the claimed shell egg. In contrast, the present invention provides a repeatable, commercially-acceptable process for reliably producing pasteurized shell eggs with no more than insignificant coagulation of the albumen and the yolk of the shell egg. According to the present

invention, any significant level of coagulation among the processed eggs would render the pasteurization method, and the shell eggs thereby produced, unsuitable for commercial purposes (see, e.g., the Ball Declaration executed January 3, 1997, ¶ 13).

Moreover, with respect to Van Lith *et al.*, the Examiner states that "Van Lith *et al.* indicates that egg white coagulation is effected when heating at the combination of above 57 C and 20 minutes, it does not set forth at what point above 57 C and 20 minutes this actually occurs (e.g. 58 C and 24 minutes?)." (Final Official Action, page 4, lines 14-17). Appellants respectfully submit that this type of conjecture is not appropriate in the anticipation analysis. A finding of anticipation cannot be based on mere speculation. The explicit teachings of Van Lith *et al.* are as follows:

From the calculated internal temperatures, it could already be expected, that this heat treatment in water [at 57° C] never could be effective to destroy Salmonella bacteria if present. The results in Table 3 confirm this finding. (page 159, Col. 1, paragraph 5; emphasis added).

Pasteurization of table eggs at 57 °C using the method originally patented for the treatment of duck eggs to eliminate *Salmonellae* did not result in Salmonella free eggs. As the albumen coagulates strongly already at the temperature and time combination above 57°C and 20 minutes, no beneficial effect from higher temperatures of longer times can be expected. (page 159, Col. 1, paragraphs 7 and 8; emphasis added).

Thus, Van Lith *et al.* fairly teaches to one of ordinary skill in the art that thermal treatments greater than 57°C and 20 minutes result in coagulation of the albumen and, further, heat treatment in water at 57°C "never could be effective to destroy Salmonella," *i.e.*, Van Lith *et al.* teaches away from the present invention.

Accordingly, in addition to the reasons set forth above, the '939 patent does not anticipate the present invention because it does not enable one

skilled in the art to make and use the claimed shell eggs. See MPEP § 2121.01; *In re Donohue*, 226 USPQ 619 (Fed. Cir. 1985); *In re Hoeksema*, 158 USPQ 596 (CCPA 1968). Such a conclusion is confirmed by the Van Lith *et al.*, Stadelman *et al.*, and Hou *et al.* references, discussed above, which clearly indicate that those skilled in the art did not appreciate the claimed invention as recently as 1996 and, similarly, if the '939 patent is interpreted as suggested in the present rejection, could not duplicate the results reported by Cox *et al.* in the '939 patent.

The Examiner further states that it is irrelevant whether Cox *et al.* did or did not appreciate whether or not a pasteurized egg was produced in Example 1 of the '939 patent. Appellants respond that a reference must be taken as a whole, and when the '939 patent is considered in its entirety, this reference teaches away from the present invention. Moreover, as discussed above, the legal test for inherency requires that one of ordinary skill in the art recognize the allegedly inherent teaching in the cited prior art reference. This burden has not been satisfied in the present case.

In light of the above discussion, Appellants submit that the Group I claims are patentable over the '939 patent and, therefore, request reversal of the present rejection.

B. The Group II Claim is Patentable over the '939 Patent

The Group II claim is Claim 25, which depends from Claim 24. The Group II claim includes each of the recitations of the Group I claims and, therefore, is patentable at least per the patentability of the Group I claims. As discussed above, the conditions relied upon by the Examiner would not result in a shell egg having at least a 5D reduction in *Salmonella enteritidis* in the albumen and yolk of the egg, much less at least a 7D reduction as recited by the Group II claim. Appellants submit that, as the cited condition of the '939 patent (*i.e.*, 57 °C for 40 to 45 minutes) does not provide a shell having at least a 7D reduction in *Salmonella enteritidis* in the albumen and yolk of the

shell egg, the '939 patent does not anticipate the Group II claim. Accordingly, Appellants submit that the rejection of the Group II claim should be reversed for at least these additional reasons.

C. The Group III Claim is Patentable over the '939 Patent

The Group III claim is Claim 26, which depends from Claim 24. The Group III claim includes each of the recitations of the Group I claims and, therefore, is patentable at least per the patentability of the Group I claims. As discussed above, the conditions relied upon by the Examiner would not result in a shell egg having at least a 5D reduction in *Salmonella enteritidis* in the albumen and yolk of the egg, much less at least a 9D reduction as recited by the Group III claim. Appellants submit that, as the cited condition of the '939 patent (*i.e.*, 57 °C for 40 to 45 minutes) does not provide a shell having at least a 9D reduction in *Salmonella enteritidis* in the albumen and yolk of the shell egg, the '939 patent does not anticipate the Group III claim. Accordingly, Appellants submit that the rejection of the Group III claim should be reversed for at least these additional reasons.

D. The Group IV Claim is Patentable over the '939 Patent

The Group IV claim is Claim 28, which depends from Claim 24. The Group IV claim includes each of the recitations of the Group I claims and, therefore, is patentable at least per the patentability of the Group I claims. Furthermore, the Group IV claim further recites that the shell egg "has a refrigerated shelf life of at least about 12 weeks." The Official Actions in the present case have never expressly addressed the recitations of Claim 28. Accordingly, Appellants submit that a *prima facie* case of anticipation has not been established with respect to Claim 28. Furthermore, Appellants submit that in light of the express teachings of the '939 patent, a *prima facie* case may not be properly made.

Appellants note that Example 1 of the '939 patent makes no mention of shelf life or the extension of shelf life. However, in discussing the hyperpasteurization methods suggested by Cox *et al.*, the '939 patent expressly states that:

While the foregoing approach will provide a reasonable degree of improved food safety, particularly with respect to destruction of Salmonella and to decreased oxygen tension if inert gases are used to replace indigenous ones, **it cannot provide improved safety or keeping** in the event of contamination by some other types of microbes or against very high initial concentrations of other microbes.

'939 patent, col. 15, lines 43-50, emphasis added. Accordingly, in light of the express acknowledgement in the '939 patent that the approach of Cox *et al.* cannot provide improved keeping (*i.e.* extended shelf life), Appellants submit that the '939 patent does not disclose or suggest a shell egg with a 12 week shelf life as recited in the Group IV claim. To find such a teaching in the '939 patent would be to impermissibly ignore the teachings of the '939 patent itself. Accordingly, Appellants submit that the rejection of the Group IV claim should be reversed for at least these additional reasons.

E. The Group V Claim is Patentable over the '939 Patent

The Group V claim is Claim 29, which is an independent claim which recites:

29. A thermally treated shell egg wherein said shell egg received a thermal treatment sufficient to cause at least about a 5D reduction in *Salmonella enteritidis* in the albumen and in the yolk of said shell egg but insufficient to cause more than insignificant coagulation of the albumen and the yolk of said shell egg, wherein said shell egg has an essentially natural proportion of indigenous gases therein.

The Group V claim includes each of the recitations of the Group I claims and, therefore, is patentable for the same reasons the Group I claims are patentable. Furthermore, the Group V claim further recites that the "shell egg has an essentially natural proportion of indigenous gases therein."

Appellants submit that it is at most unclear from the '939 patent whether the studies of Example 1 were carried out by the eggs being subjected to hypobaric pressures to remove the indigenous gases. As discussed above, the Examples are described in the '939 patent as illustrative of "hyperpasteurization." ('939 patent, col. 15, lines 51-61). Further, hyperpasteurization is defined in the '939 patent as shell eggs which are "subjected to hypobaric pressure to substantially disinfuse indigenous dissolved gases." ('939 patent, col. 14, lines 62-65). Example 1 of the '939 patent is silent as to whether the eggs were subject to hypobaric pressure or not. As such, Appellants submit that, given the description of the examples as "examples of 'hyperpasteurization'," a reasonable interpretation of the '939 patent is that Example 1 is an example of hyperpasteurization which involved removing the indigenous gases from the shell egg. In any event, as it is reasonable to conclude that the shell eggs of Example 1 did not have essentially the natural proportions of indigenous gases Example 1 cannot anticipate the Group V claim. Anticipation cannot be based on speculation and it does not necessarily follow from the discussion of the examples in the

'939 patent, when read in light of the recitations beginning at col. 14, line 62 and continuing to col. 15, line 61 which introduces the examples, that the shell eggs of Example 1 had the natural proportion of indigenous gases.

Accordingly, Appellants submit that the rejection of the Group V claims should be reversed for at least these additional reasons.

F. The Group VI Claim is Patentable over the '939 Patent

The Group VI claim is Claim 30, which is an independent claim which recites:

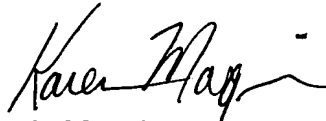
30. A thermally treated shell egg wherein said shell egg received a thermal treatment sufficient to cause at least about a 5D reduction in *Salmonella enteritidis* in the albumen and in the yolk of said shell egg but insufficient to cause more than insignificant coagulation of the albumen and the yolk of said shell egg, wherein said thermal treatment was applied under atmospheric pressure.

The Group VI claim includes each of the recitations of the Group I claims and, therefore, is patentable for the same reasons the Group I claims are patentable. Furthermore, the Group V claim further recites that the thermal treatment provided to the shell egg "was applied under atmospheric pressure." Appellants submit that, as discussed above with reference to the Group V claim, the '939 patent is unclear as to whether hypobaric pressure was applied to the shell eggs. Accordingly, anticipation cannot be based on speculation that hypobaric pressure was not applied to the shell eggs. As such, Appellants submit that the Group VI claim is patentable over the '939 patent and request withdrawal of the rejection for at least these additional reasons.

V. Conclusion.

In light of the above discussion, Appellants submit that the rejection of the present claims should be reversed and the present application passed to issue.

Respectfully submitted,



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Enclosures: Appendix A (pending claims)
Appendix B (Schuman *et al.*)

Customer No.

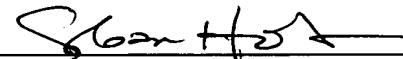


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Sloan Hobbs